

Remarks

In the above-identified Office Action, Examiner Kennedy rejected the pending claims principally over U.S. Patent No. 5,830,195 to Peters et al. He also rejected some of the claims on a new ground under Section 112, which was not necessitated by amendment. As Examiner Kennedy takes up this case again, he is respectfully requested to call the undersigned counsel for a telephone interview.

The Objection to the Abstract Should Be Withdrawn

Examiner Kennedy's comments concerning with his objection to the Abstract were not entirely understood, and it is believed that the Abstract as it currently stands meets the requirements of the rules. Nevertheless, an effort has been made to amend it to meet the Examiner's comments, and withdrawal of the objection is respectfully requested.

The Finality of the Present Action Should Be Withdrawn

A second Office Action is properly final except "where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims, nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p)." MPEP 706.07(a). Even if a new rejection is based on a reference in an IDS as described, a subsequent action cannot be final if "[an]other new ground of rejection which was not necessitated by amendment to the claims is introduced by the examiner." Id., citing MPEP 609.04(b).

In this case, Examiner Kennedy made a new ground of rejection under Section 112 of claims 2, 7, 10 and 17, alleging that they are indefinite in the word "finlike." That language was present in those claims previously, i.e., no amendment was presented adding or changing that

language in the response to the first Office Action. There was no amendment that necessitated the new Section 112 ground of rejection, and so the finality of this action is premature.

The Section 112 Rejection Should Be Withdrawn

Claims 2, 7, 10 and 17 were newly-rejected as allegedly indefinite for use of the term “finlike.” While Examiner Kennedy referred to MPEP 2173.05(d) in this rejection, respectfully the claim does not use “for example,” “such as” or other exemplary language. Further, the specific examples listed in that section are not *per se* rules, per MPEP 2173.05(d) and 2173.02. Rather, the test is whether a claim is “insolubly ambiguous without a discernable meaning after all reasonable attempts at construction.” *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1366, 71 USPQ2d 1081, 1089 (Fed. Cir. 2004), *cited in* MPEP 2173.02. The MPEP notes that the claim language must be analyzed in light of the specification. *Id.* A “claim term that is not used or defined in the specification is not indefinite if the meaning of the claim term is discernible.” *Id.* (citing *Bancorp Svcs., LLC v. Hartford Life Ins. Co.*, 359 F.3d 1367, 1372, 69 USPQ2d 1996, 1999-2000 (Fed. Cir. 2004)).

In the present case, the term “finlike” is used throughout specification with cross-reference to the drawings. The specification has both textual and visual information by which the term can be interpreted. Respectfully, the statement that these claims include elements not actually disclosed is incorrect, since “finlike” handles are seen in the application.

Claims 2-4, 6-7 and 9-25 are Not Anticipated by Peters

Peters does not anticipate independent claims 11 and 14 and their dependent claims, since it does not show all features recited in them. Withdrawal of this rejection is respectfully requested.

Item 25 of Peters is not part of a “locking member” that makes a luer connection assembly.” Peters explains that item 1-11 in its drawings are the general “luer lock,” col., 4, ll. 3-5. Item 25 is added to a locking assembly in order to provide the ratchet and pawl action on which its disclosure centers. Peters’ goal is to add to the locking assembly separate pieces—teeth (grooves) 14, pawls 17, and sleeve 25 to force the tabs into the grooves—that cover and protect the lock 7 and male luer member 2 from counterclockwise turning. Respectfully, one of ordinary skill reading Peters would not view item 25 as part of a “locking member” as recited.

Further, claim 11 recites that “the locking member can in assembly of the connector assembly be moved from a rearward end of the luer fitting member toward the forward end thereof, with said protrusion snapping over said conical restraining surface” Nothing in Peters explicitly discloses that items 7 and 25 are assembled as recited. That assembly is not inherent in the reference either, since it is possible to insert the end 5 of Peters’ male luer member through the hole of wall 9, bending flange 10 to enable it to get through the hole.

For at least these reasons, Peters does not include all features of independent claims 11, 14 and 25. Nevertheless, in order to move this application more quickly to allowance, the above amendments are being made. As discussed below, the amended claims are allowable over the cited references.

The locking member is defined to be of a single piece. The Office Action relied on both item 7 and item 25 of Peters as a “locking member.” If both of those items must be combined to be a “locking member,” then Peters does not anticipate claim 11 as amended. If only item 7 is considered a “locking member,” it does not include all of the features of the recited locking member. For example, item 7 does not extend axially beyond at least a portion of a conical restraining surface and toward the forward end of its item 2.

Moreover, Peters relies on the separateness of items 7 and 25 for its described operation. Item 25 moves forward over item 7 in order to force pawls 17 toward grooves 14. As already noted, Peters' focus is to provide external grooves and pawls within the grooves over and around items 7 and 2 that will prevent unwanted turning of item 7. Without the relative movement between items 7 and 25, the interaction between pawls 17 and grooves 14 cannot occur, defeating Peters' main purpose. It thus would not have been obvious to anyone of ordinary skill in this art to combine items 7 and 25 into a single piece.

The remaining claims in this rejection are dependent from claim 11 or claim 14, and are thus also allowable on that basis and/or on their own merit. For example, claim 2 recites that the locking member comprises a finlike handle. The Office Action suggested that Peters shows a "finlike" handle, but there is no textual disclosure of such a handle, and none of Peters' drawings show a full outside view of its item 25. At best, the cross-sections of Figures 4 and 7 of Peters suggest only a cylindrical configuration, with what appear to be otherwise-undefined depressions (see the far left of Figure 4 and the far right of Figure 7). Those Figures appear to be inconsistent with Figure 8, which shows an entirely cylindrical item 25.

Likewise, Peters' figures do not show an undulating grip of a locking member, as recited in claim 3. The cross-sections of the drawings do not include enough information to determine whether item 25 undulates. In particular, the region above the hatched area left of the number 25 in Figure 4 suggests only a surface of some kind visible behind the hatched "cut" of the cross-section. No information is given in the drawing or specification about the configuration of that surface, or of any other unseen part of item 25.

As to claim 4, Figure 9 of this application shows an example of a skeletal handle (see also paragraphs 46-47), and the specification differentiates between a skeletal handle and other types

of handles (see, e.g., paragraphs 61-64). With due respect, “skeletal handle” is a proper structural limitation, which is not found in the Peters reference.

As with claims 2 and 3, Peters does not show enough information for one to determine that its item 25 has an indentation approximating the shape of a human thumbprint, as recited in claim 6. The left of Peters’ Figure 4 shows only an upwardly-curving line in cross-section, apparently with a surface of some kind behind it. There is no disclosure in the drawing or in the specification of any dimensional shape of that surface, much less that it might represent a thumbprint.

Claim 7 recites that the finlike handle radially extends outward from approximately one longitudinal end of the locking member. Figure 4 of Peters shows a cylindrical item 25 (as does its Figure 8). Nothing extends radially outward from it.

As to claims 9 and 10, the above remarks establish that they are not anticipated by Peters. Moreover, nothing in Peters shows or suggests a combination of handle types or configurations on one locking member. Again, since item 25 is only shown in cross-sectional view in Figures 4 and 7 and as a cylinder in Figure 8, there is insufficient information to establish the features of claims 9 and 10 in Peters.

Claim 12 recites that the annular surface uniformly mates with a corresponding annular surface of the plateau shaped protrusion. The Office Action refers to column 3, line 67-column 4, line 3 in this regard, but that disclosure only states that “end wall 9 . . . can be held captive by a further projection 11 on the member 2 although this is not essential.” Nothing in that textual passage discloses uniform mating as recited in claim 12.

Claims 15-20 depend from independent claim 14, and are not anticipated by Peters on that basis and/or on their own merit. Claim 15 recites that the annular surface uniformly mates

with a corresponding annular surface of the plateau shaped protrusion. As discussed above with respect to claim 12, the noted parts of Peters do not show that feature.

Claims 17-19 recite examples of handles shown in the present application. As discussed above, Peters does not include enough information to show or suggest those structures. Peters also does not show a rim in a locking member as recited in claim 23.

Claim 8 is Not Obvious over Peters With or Without Werschmidt

The Office Action alleged claim 8 to be obvious over Peters in view of the previously-cited Werschmidt reference. It acknowledged that Peters does not show ten waves in an undulating grip, but it did not cite any part of Werschmidt for any disclosure. In fact, the Office Action made no reference to Werschmidt at all other than citing its number.

As noted above, Peters does not show all features of independent claim 11. The Office Action's lack of any citation to specific portions of Werschmidt, as required to support an obviousness rejection, shows that a *prima facie* basis for the rejection has not been made, and further Applicants do not know what aspects of Werschmidt to discuss. It is noted that Figures 1 and 2 of Werschmidt do not disclose the features of claim 11 (or claim 8) missing from Peters. Further, Peters does not disclose any undulations on its item 54. The fact that it does not disclose any structural or functional significance to the number of undulations (as alleged by the Office Action) indicates a lack of disclosure, not a state of mind of one of ordinary skill in the art as to a number of undulations. Respectfully, there is no evidence in the record to support the Office Action's conclusion that the subject matter of claim 8 is (1) merely a change in shape or (2) that it would yield expected and predictable results.

New Claims

Claims 26-27 depend from claim 11, and are fully supported by the present application. Claim 26 recites that the locking member extends along the luer fitting member on both sides of the conical restraining surface. Support for that language is found particularly in Figures 1 and 2 and related text. It is allowable over Peters at least based on its dependence from claim 11, and on its own merit. Peters does not show a one-piece locking member that extends on both sides of a conical restraining surface. Peters' item 7 does not extend on both sides of any conical restraining surface, and its item 25 is not a locking member by itself.

Claim 27 recites that the luer fitting member includes a tubular surface forward of the conical restraining surface, and a non-orthogonal surface adjoining the tubular surface that generally faces distally. Support for that language is found throughout the application, and particularly in Figures 1 and 2 and related text. It is allowable over Peters at least based on its dependence from claim 11, and on its own merit. For example, Peters does not show or suggest a distally-facing non-orthogonal surface as described. Peters' item 10 has a distally-facing surface that is orthogonal to the longitudinal axis, and thus if it is pressed against female part 6 results in a seal over a substantial area that is difficult to release when disconnection of items 2 and 6 is desired. A surface as recited in claim 26 does not result in such a firm seal if pressed against the other luer member, and when disconnection is necessary any contact between the recited surface and the other luer member does not add to the force required to separate them.

Conclusion

It should be understood that the above remarks are not intended to provide an exhaustive basis for patentability or to concede any basis for the rejections in the Office Action but are

simply provided to address the rejections made in the Office Action in an expedient fashion. Applicant reserves the right to later contest positions taken by the Examiner that are not specifically addressed herein. No narrowing amendments necessary to patentability have been made in this paper, and no narrowing through any remarks herein is intended or should be inferred.

Reconsideration and passage to allowance in view of the above amendments and remarks is respectfully requested.

Respectfully submitted,

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